UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/337,675	06/22/1999	JON SWANSON	029318/0497	9275

31049 7590 01/11/2011

Elan Drug Delivery, Inc. c/o Foley & Lardner
3000 K Street, N.W.
Suite 500
Washington, DC 20007-5109

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
01/11/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/337,675	SWANSON ET AL.	
	Examiner	Art Unit	
	S. TRAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-22,25-36,38-40,42-44,46-48 and 50-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-22,25-36,38-40,42-44,46-48 and 50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/08/10;12/08/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

Claims 1, 2, 4, 8-13, 30-36, 38-40, 46-48 and 50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al. WO 96/20698 A2.

Levy teaches a biodegradable controlled release nanoparticles comprising a nanoparticulate drug composition and at least one high molecular weight polymer (abstract, pages 7-8; and claims). The nanoparitcles have average diameter less than 300 nm (page 6, lines 13-18). Levy also teaches that the polymer is incorporated in the nanoparticles as a polymer matrix (page 7, lines 1-7; and page 22, lines 18 through page 23, lines 1-5). Drugs are disclosed in pages 11-12. Drug composition also comprises a surface modifying agent that adsorbing or adhering on the nanoparticles (pages 12-15; and page 20, lines 11-20). The nanoparticles are incorporated in an oral dosage form that releases the drug in periods of time ranging from 4-9 hours (page 107, lines 5-11; and page 110). The oral dosage form such as capsule is coated with enteric polymers such as cellulose acetate phthalate, shellac, and Eudragit polymers for controlling the release time of the drug (page 106, lines 5 through page 107, lines 1-11).

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48 and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al., in view of Liversidge et al. WO 99/02665 A1.

Levy is relied upon for the reasons stated above. Levy does not teach tablet comprising nanoparticles, and pharmaceutically acceptable excipients.

Liversidge teaches a solid dosage form comprising: 1) nanoparticulate drug having effective average particle size less than about 1000 nm, preferably less than 400 nm; and 2) binder, filler, lubricant, disintegrant, and other excipients (page 5, paragraphs 2-6; and page 7, paragraphs 2-3). Liversidge further teaches a process for preparing the solid dosage form (page 16, last paragraph through page 19).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the nanopartilces of Levy, to include the use of pharmaceutical excipients. This is because Liversidge teaches that it is well known to include excipients such as binder, filler, lubricant, disintegrant and other excipients in an oral dosage form, and because Levy teaches the desirability for incorporating the nanoparticles into an oral dosage form.

Response to Arguments

Applicant's arguments filed 11/08/10 have been fully considered but they are not persuasive.

Applicant argues that the biodegradable controlled release nanoparticles described by Levy are structurally distinguishable from the claimed composition. More specifically, the active agent of Levy is "incorporated, embedded, or entrained" in a polymer matrix. In contrast to the claimed invention, in which a surface modifier is associated with the surface of the drug particle, in the composition of Levy surface

modifying agents are "attached to the surface of the polymer core." Levy, page 7, 1st paragraph. As such, Levy's disclosure fails to meet the claim limitation of "at least one surface stabilizer associated with the surface of the drug particles." In fact, it is unlikely for Levy's surface modifying agent to have direct contact with, let alone associated with the surface of, the active agent because the active agent of Levy is embedded in the polymeric core.

In response to Applicant's arguments however, Applicant's attention is called to Examples 1 and 2, which disclose that the active agent, e.g., indinavir, came in direct contact with the surface stabilizer solution. From these examples, it can be concluded that the surface modifying agent does associate wit the drug particle.

Applicant argues that the surface stabilizer of Applicants' invention functions as a steric hindrance to maintain the small particle size of the active agent by adhering to the surface of the active agent particles. *See* specification, at page 12. In marked contrast, the surface modifying agent of Levy's composition "assist[s] in targeting the nanoparticles to a desired site *(e.g.,* as an antibody) or in retaining the nanoparticles at the site *(e.g.,* as a cell adhesive)" (page 7, lines 5-7). In view of Levy's teaching, one skilled in the art would not have equated the surface stabilizer of the claimed invention with the surface modifying agent of Levy's composition because they have entirely different functions in the respective compositions. Because the prior art fails to teach each and every aspect to anticipate the claimed invention, Applicants respectfully request withdrawal of the rejection.

However, in response to applicant's argument that Levy fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., surface stabilizer that functions as a steric hindrance to maintain the small particle size of the active agent by adhering to the surface of the active agent particles) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, it is noted that Levy teaches the claimed surface stabilizing agent. See pages 10-11. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

With respect to the 103(a) rejection, Applicant argues that the teachings of Levy are discussed *supra.* Liversidge is cited for the alleged teaching of tablets and pharmaceutically acceptable excipients but fails to compensate for the deficiencies of Levy. Accordingly, Applicants respectfully request the withdrawal of the rejection.

However, in response to applicant's Arguments, as discussed above, Levy teaches the claimed surface stabilizer that comes in contact with the active particles. Thus, the 103(a) rejection over Levy in view of Liversidge is matained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. TRAN whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. TRAN/
Primary Examiner, Art Unit 1615